DEPARTMENT OF HEALTH AND HUMAN SERVICES

93784d

Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Boulevard
Nashville, TN 37217 JEH

January 7, 2003

VIA FEDERAL EXPRESS – NEXT DAY

Ms. Elizabeth A. Westmoreland
Mr. Robert H. Matthews, Jr.
Co-Owners
Complete Care, Inc.
503 Gault Avenue, South
Fort Payne, AL 35968

Warning Letter No. 03-NSV- 05

Dear Ms. Westmoreland and Mr. Matthews:

During an inspection by the Food and Drug Administration (FDA) of your oxygen gas transfilling facility on December 18-23, 2002, our investigator documented deviations from the Current Good Manufacturing Practice Regulations, Title 21 Code of Federal Regulations (CFR) Part 211, which cause your medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection revealed a failure to conduct an identity test on bulk liquid oxygen and at least annually verify the reliability of your supplier's analysis [21CFR 211.84(d)], no batch production records for transfilling of liquid oxygen into cryogenic home units [21CFR 211.188], no quality control unit [21CFR 211.22(a)], inadequate Good Manufacturing Practice training of firm personnel [21CFR 211.25(a)], inadequate labeling accountability [21CFR 211.125(c)], no written procedures for the warehousing of compressed oxygen gas cylinders and liquid oxygen cryogenic home units [21CFR 211.142(a)], and inadequate Standard Operating Procedures [21CFR 211.80(a)].

The inspection also revealed that your cryogenic vessels failed to bear the required labeling. You were placing Compressed Oxygen USP labels on Liquid Oxygen USP cryogenic home units. We are enclosing a copy of a proposed label for your Liquid Oxygen units.

Our inspection further determined that your facility was not currently registered with FDA. Therefore, the medical oxygen transfilled by your facility is misbranded under Section 502(o) of the Act in that it is transfilled in an establishment not duly registered under Section 510 of the Act. Your medical oxygen also has not been listed as required by Section 510(j) of the Act. We are enclosing registration and listing forms for your use.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing

Practice regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in FDA initiating regulatory action, including seizure and/or injunction, without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217,

Sincerely,

Howard E. Lewis
Acting Director, New Orleans District

HEL:JEH:bds

Enclosures:
21CFR Part 211
Compressed Medical Gases Guidelines
Proposed Liquid Oxygen label
Form FDA 2656 – Registration of Drug Establishment
Form FDA 2657 – Drug Product Listing
Drug Registration and Listing Instructions